FDA's Sentinel Initiative — A National Strategy for Monitoring Medical Product Safety

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Sentinel Initiative

Develop a national electronic safety monitoring system

- Strengthen FDA's ability to monitor postmarket performance of medical products
- Enable FDA to access existing automated healthcare data by partnering with data holders (e.g., insurance companies with large claims databases, owners of electronic health records, others)

Will augment, not replace, existing safety monitoring systems

Potential Capabilities of Sentinel

- Improving FDA's capability to identify and evaluate safety issues in near real time
- Enhancing FDA's ability to evaluate safety issues not easily evaluated with the passive surveillance systems currently in place
  - Expanding FDA's access to subgroups and special populations (e.g., pediatrics, geriatrics)
  - Expanding FDA's access to longer term data
  - Expanding FDA's access to adverse events occurring commonly in the general population (e.g., myocardial infarction, fracture) that tend not to get reported to FDA through its passive reporting systems

Mini Sentinel

Harvard Pilgrim Healthcare

Develop and test the scientific operations needed for the Sentinel Initiative.

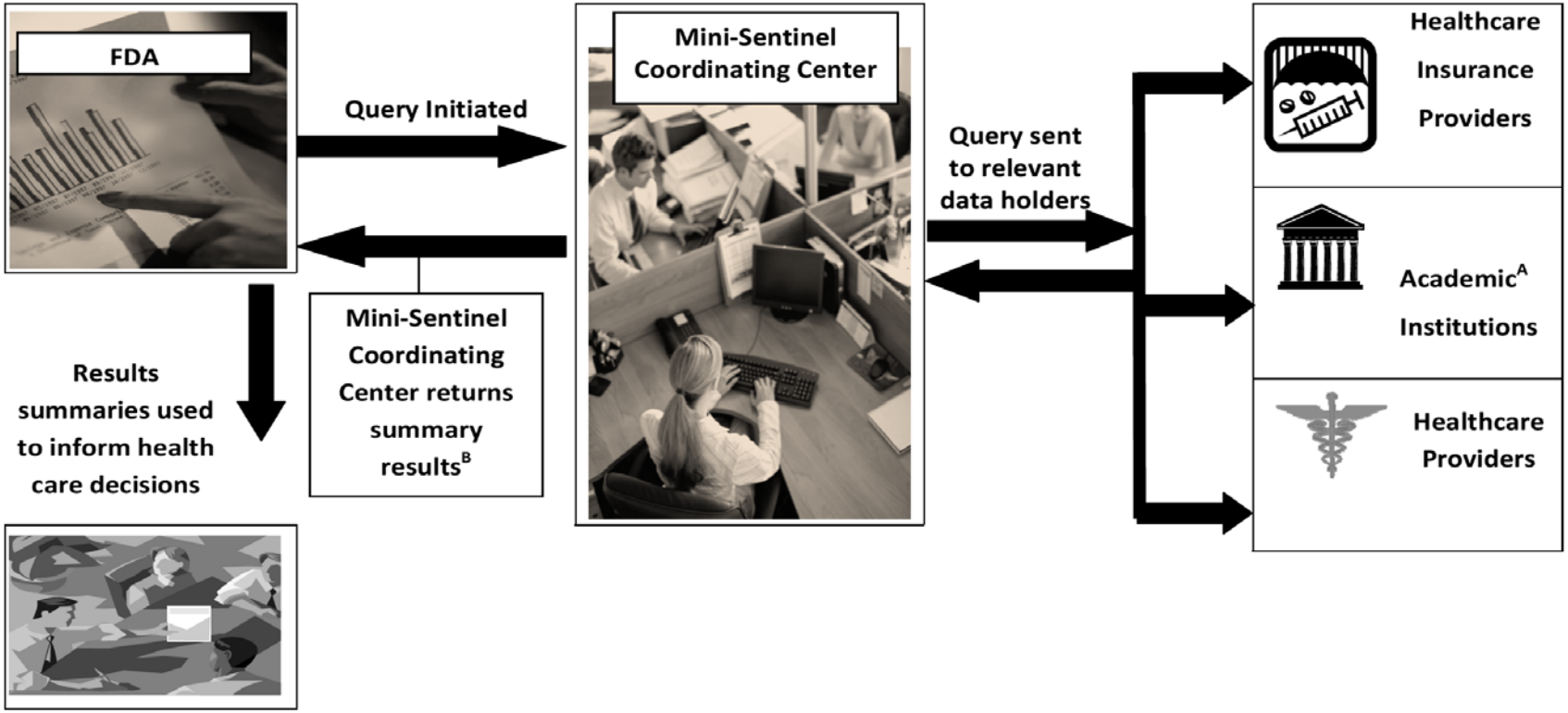
Create a coordinating center with continuous access to automated healthcare data systems to enable safety evaluations

Organizations

America's Health Insurance Plans
CIGNA Healthcare
Cincinnati Children's Hospital Medical Center
Critical Path Institute
Brigham and Women's Hospital
- Division of Pharmacoepidemiology and Pharmacoeconomics
- Division of General Medicine

Duke U School of Medicine
HMO Research Network:
Group Health Research Institute
Harvard Pilgrim Health Care Institute
Henry Ford Research Foundation
HealthPartners Research Foundation
Lovelace Clinic Foundation
Marshfield Clinic Research Foundation
Meyers Primary Care Inst(UMass / Fallon)
HealthCore, Inc
Humana - Miami Health Services Research Center
Kaiser Permanente:
Colorado, Georgia, Hawaii, Mid-Atlantic, N. California, Northwest, Ohio, and S. California regions
Outcome Sciences, Inc
Risk Sciences International
Rutgers University Inst for Health
U of Alabama at Birmingham
U of Illinois at Chicago
U of Iowa College of Public Health
U of Pennsylvania School of Medicine
Vanderbilt U School of Medicine
Weill Cornell Medical College

Overview of the Mini-Sentinel Query Process



A. Only those academic institutions with automated data will be recipients of queries.

B. No entities will have access to protected health information that they do not already hold. Instead, those whose queries are accepted by the **Mini-Sentinel Coordinating Center** for processing will receive results summaries from analyses conducted by each data holder that receives and agrees to respond to those queries. Results summaries will not include protected health information.

Mini-Sentinel major deliverables- 1st year

- A coordinating center with
  - secure communications capability for sharing confidential information between FDA and Mini-Sentinel collaborators
  - communications capability for public sharing of non-confidential work products
- The first version of the Mini-Sentinel Distributed Database, encompassing quality-checked administrative and claims data including at least 25 million lives
- A framework (taxonomy) for safety surveillance methods and a prioritized list of gaps
  - new methods development addressing three methods gaps
- A prioritized list of Health Outcomes of Interest (HOI) for subsequent validation
  - procedures for obtaining full text medical records and case adjudication for HOI
  - validation of one HOI
- A fully developed protocol to use accumulating data for identify excess risk of acute myocardial infarction associated with one or more drugs

Pediatric patients included in the Mini-Sentinel Distributed Database*

Age Groups	# of Pediatric Patients Captured in Distributed Partners' Databases as of January 1, 2009
0 - 4 weeks	24,398
5 - 52 weeks	284,324
1 - 4 years	1,924,654
5 - 9 years	3,042,707
10 - 19 years	7,029,473

*Distributed partners include HMO Research Network, Kaiser Permanente, Humana, and Healthcore

Federal Partners Collaboration

An active surveillance initiative via intra-agency agreements with CMS, VA, DoD

- Pediatric data available in Medicaid and DoD databases

Small distributed system

- Each Partner has unique data infrastructure
- No common data model being utilized

FDA proposes medical product – AE pairs to evaluate

Develop a shared protocol

Evaluate active surveillance methodologies

Assess interpretability of query findings resulting from a decentralized analytic approach

Pediatric Patients included in DoD's Pharmacovigilance Defense Application System

Age Groups	Pediatric Patients Eligible for Care as of March 2010
0 - 21 years	2,872,445
0 - 17 years	2,074,821
0 - 4 weeks	8,967
5 - 52 weeks	114,722
1 - 4 years	497,833
5 - 9 years	551,808
10 - 17 years	901,491
18 - 21 years	797,624

Demographic Characteristics of Medicaid FFS Beneficiaries with Drug Coverage and Claims Capturing Health Outcomes - 2009

Population (millions)	2009 Continuous FFS Enrollment Period of at Least:			
	1 month	3 months	6 Months	12 Months
Total (all ages)	**39.8**	**33.1**	**26.3**	**21.2**
0 - 21 years	19.8	15.6	11.6	9
0 - 17 years	16.8	13.2	9.7	7.7
0 - 4 weeks	1.2	0	0	0
5 - 52 weeks	2.2	1.7	1	0.5
1 - 4 years	4.9	3.9	3	2.4
5 - 9 years	4.7	3.8	2.9	2.4
10 - 17 years	6.4	5.1	4	3.3
18 - 21 years	3.4	2.8	2.2	1.6

Other ongoing activities

- Convener on Active Medical Product Surveillance- The Brookings Institution
  - Holds expert panels, active surveillance roundtables, implementation meetings, and annual Sentinel public meeting
- Observational Medical Outcomes Partnership
  - A Public-Private partnership focused on developing the data infrastructure and scientific methods needed for conducting active surveillance in observational data

Conclusions

- Pediatric population is well represented in the Mini-Sentinel Distributed Database (MSDD) and the Federal Partners Collaboration
- Medical product safety issues unique to the pediatric patient population can be addressed within the Sentinel Initiative pilot programs
  - Some questions such as growth-related concerns will need to await the addition of more clinical data to the MSDD
- Broader lessons learned regarding data needs and methods development will benefit evaluations targeted at the pediatric population